

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ASTRAZENECA AB, et al.	:	CIVIL ACTION
	:	
v.	:	
	:	
MUTUAL PHARMACEUTICAL CO., INC.	:	00-4731

MEMORANDUM

Baylson, J.

August 22, 2003

AstraZeneca AB (herein “Plaintiff”) has brought this patent infringement action against Mutual Pharmaceutical Company, Inc. (“Defendant”).¹ Presently before this Court is Plaintiff’s Motion for Summary Judgment of Literal Infringement. For the reasons which follow, Plaintiff’s Motion will be granted.

I. Background and Procedural History

Plaintiff is the assignee of United States Patent 4,803,081 (“the ‘081 patent”), which was issued on February 7, 1989. The ‘081 patent contains 17 claims and relates to “extended release” pharmaceutical preparations of active compounds having very low solubility. One such compound with low solubility in the intestines is felodipine, a cardiovascular drug, which Plaintiff markets under the brand name Plendil.

On June 6, 2000, Defendant filed an Abbreviated New Drug Application (“ANDA”)

¹ The plaintiffs in this case include Aktiebolaget Hassle, KBI-E Inc., KBI Inc., AstraZeneca AB, and AstraZeneca LP. Aktiebolaget Hassle, which owns the patent at issue in this litigation, is a wholly-owned subsidiary of AstraZeneca AB. *See* Complaint ¶ 3; Defendant’s Answer, Affirmative Defenses and Counterclaim ¶ 27. KBI-E Inc. and KBI Inc., through AstraZeneca AB, have exclusive rights related to the patent in suit. *See* Complaint ¶ 6; Defendant’s Answer, Affirmative Defenses and Counterclaim ¶ 32. AstraZeneca LP is a partnership organized under the laws of Delaware. *See* Complaint ¶ 7; Defendant’s Answer, Affirmative Defenses and Counterclaim ¶ 30. In the plaintiffs’ court filings, the five plaintiff entities are referred to, collectively, as “Plaintiff” or “Plaintiffs.” Complaint ¶ 9. Accordingly, in this Memorandum, the various plaintiffs will be referred to simply as “Plaintiff.”

seeking approval from the Food and Drug Administration (“FDA”) to manufacture and sell Defendant’s proposed 10 mg generic version of felodipine. *See* Plaintiff’s Memorandum in Support of its Motion for Summary Judgment of Literal Infringement (herein “Pl. Brief”), Ex. 31 (Nov. 15, 2000 letter from Mutual to FDA). Defendant amended its ANDA twice, to apply for approval of 5 mg and 2.5 mg dosages. *See id.*

Thereafter, on September 19, 2000, Plaintiff filed this patent infringement suit, alleging that the proposed drug formulations in Defendant’s ANDA infringe the ‘081 patent. *See* 35 U.S.C. § 271(e)(2). Defendant counterclaimed, seeking declaratory judgments that its proposed formulations would not infringe the patent, and that the patent itself is invalid. On August 19, 2002, following a *Markman* hearing, this Court issued its Conclusions of Law regarding the proper construction of the patent claims at issue. Defendant then filed a motion for reconsideration, which this Court denied on October 3, 2002. On October 8, 2002, this matter was reassigned from the calendar of Judge Lowell A. Reed Jr. to the undersigned.

On October 25, 2002, Plaintiff filed its Motion for Summary Judgment of Literal Infringement. Defendant filed a brief in opposition and Plaintiff filed a reply brief. On January 30, 2003, this Court heard oral argument on Plaintiff’s motion, and the parties have since submitted supplemental briefing.

II. The Law of Patent Infringement

The relevant statute makes it an act of patent infringement to file an ANDA,

if the purpose of such submission is to obtain approval [under the Food, Drug and Cosmetic Act] to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in [the] patent or the use of which is claimed in [the] patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). The remedies for this type of infringement include injunctive relief against the Defendant's commercial manufacture, use, or sale of the drug. *See id.* § 271(e)(4). A court may also order that the effective date of approval of the Defendant's new drug application be no earlier than the expiration of the infringed patent. *See id.* Monetary damages may not be awarded based on this type of infringement unless the Defendant has already commercially made, used, sold or offered to sell the drug. *See id.* Defendant admits that it filed its ANDA with the purpose of eventually selling a generic version of felodipine. *See* Defendant's Answer, Affirmative Defenses and Counterclaim ¶¶ 12-14. Defendant further admits that its ANDA contained a certification, as required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV), declaring that Defendant's products would not infringe the '081 patent. *See id.* The question thus becomes whether the felodipine formulations described in Defendant's ANDA were claimed in the '081 patent.

Courts follow a two-prong analysis in determining whether a patent has been infringed. First, the court construes the scope and meaning of the claims within the patent itself, as a matter of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976-978 (Fed. Cir. 1995), *aff'd* 517 U.S. 370 (1996). Second, the court compares the claims of the patent to the allegedly infringing product, to determine whether it infringes the patent, either literally, or by equivalent parts. *See, e.g., id.*

In the first step, to ascertain the meaning of the patent's claims, the court must consider the language of the claims, the patent's specification, and the prosecution history. *See id.* at 979. The court may also rely on extrinsic evidence, such as dictionaries, learned treatises and expert

testimony concerning the interpretation that those skilled in the relevant art would give to the claims. *See id.* at 980.

Terms within a patent claim must be interpreted according to “their ordinary meaning to one of skill in the art unless it appears from the patent and file history that the terms were used differently by the inventors.” *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387 (Fed. Cir. 1992). As the Federal Circuit has recently explained,

This heavy presumption in favor of the ordinary meaning of claim language as understood by one of ordinary skill in the art is overcome: (1) where the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term; or (2) where the term chosen by the patentee so deprives the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used.

Prima Tek II, L.L.C. v. Polypap, S.A.R.L., No. 02-1164, 2003 WL 245558, at *3 (Fed. Cir. Feb. 5, 2003).

A patent’s prosecution history consists of the public record of proceedings in the Patent and Trademark Office (“PTO”). *See Markman*, 52 F.3d at 980. Courts assess whether an inventor waived coverage of certain subject matter based on the totality of the prosecution history, including both claim amendments and arguments made to the PTO. *See Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1326 (Fed. Cir. 2002). The prosecution history can only limit claim language where the inventor surrendered coverage “with reasonable clarity and deliberateness.” *Schumer v. Laboratory Computer Systems, Inc.*, 308 F.3d 1304, 1313 (Fed. Cir. 2002).

In the second step of the two-prong process, the court compares the elements of the patent claims to the allegedly infringing product. The general rule is that a patent claim covers an accused device if that device embodies every element of the claim, either literally or by an

equivalent element. *See, e.g. Carroll Touch, Inc. v. Electro Mechanical Systems, Inc.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993); *Mannesmann Demag Corp. v. Engineered Metal Products*, 793 F.2d 1279, 1282 (Fed. Cir. 1986). Plaintiff in the instant case is proceeding on a theory of literal infringement. To succeed, Plaintiff “must show that the accused device contains every limitation in the asserted claims. . . . If even one limitation is missing or not met as claimed, there is no literal infringement.” *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998). *See also Mannesmann*, 793 F.2d at 1282. Though this infringement question is typically for the fact finder, *see id.*, it becomes amenable to summary judgment where the parties do not dispute any relevant facts regarding the accused product, *see, e.g., General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 983 (Fed. Cir. 1997), or when the Court finds “no genuine issue as to any material fact” for trial. Fed. R. Civ. P. 56(c). An issue is “genuine,” under Rule 56(c), if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

A party seeking summary judgment always bears the initial responsibility for informing the district court of the basis for its motion and identifying those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party’s initial burden can be met simply by “pointing out to the district court that there is an absence of evidence to support the non-moving party’s case.” *Id.* at 325. After the moving party has met its initial burden, “the adverse party’s response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial.” Fed. R. Civ. P. 56(e). Summary judgment is appropriate if the non-moving party

fails to rebut by making a factual showing “sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.”

Celotex, 477 U.S. at 322. Under Rule 56, the Court must view the evidence presented on the motion in the light most favorable to the opposing party. *Anderson*, 477 U.S. at 255.

III. Step One – Claim Construction

This Court has already completed the first step of the patent infringement analysis. *See* Conclusions of Law Regarding Patent Claim Construction (Aug. 19, 2002) (herein “Conclusions of Law”). In his August 19, 2002 opinion, Judge Reed ruled as to the meanings of several terms used in claims 1, 8, 12, 14, 15 and 17 of the ‘081 patent – the only claims at issue in this litigation. *See id.* at 1. Most of the terms interpreted by Judge Reed appear in claim 1 of the patent. Claims 2 through 16 are dependent on claim 1, which contains the following limitations:

1. A solid preparation providing extended release of an active compound with very low solubility in water *comprising a solution or dispersion* of an effective amount *of the active compound* in a semi-solid or liquid nonionic *solubilizer, wherein* the amount by weight of the solubilizer is at least equal to the amount by weight of the active compound, *and* a release controlling system to provide extended release.

United States Patent 4,803,081 (issued Feb. 7, 1989) (emphasis added).

A. This Court’s Claim Construction

1. Basic Terminology

In his Conclusions of Law Judge Reed construed the term “extended release,” throughout the patent, as meaning “releasing the active ingredient from the dosage form over time in a manner that reduces the dosage frequency as compared to immediate release dosage forms.”

Conclusions of Law at 21. The Court interpreted the terms “solution or dispersion” and

“dissolving or dispersing” according to their ordinary meanings, such that “a solution or dispersion is the dispersed or dissolved substance(s) and the medium in which it is dispersed or dissolved.” *Id.* at 23. Next, the Judge interpreted “hydrophilic gel system,” appearing in claim 12 of the patent, to mean “a delivery system of a water-soluble gel- and matrix-forming material.” *Id.* at 24. Finally, the Court construed the term “pharmaceutical dosage unit,” in claim 17, as meaning simply a dosage form, such as a tablet or capsule, containing a dose of a drug. *Id.* at 25.

2. “Nonionic Solubilizer”

The bulk of Judge Reed’s opinion, however, concerned the term “nonionic solubilizer.” The parties have not disputed the meaning of “nonionic.” *See* Conclusions of Law at 10. Providing more than ten pages of reasoning and support, the Court held that “solubilizer,” throughout the patent, should be interpreted according to its “ordinary” meaning: a compound “that increases the solubility of a substance in a particular solvent.” *Id.* at 19.

Significantly, Judge Reed found that the ordinary meaning of “solubilizer” includes both “surfactants” and “co-solvents.” Conclusions of Law at 10, 14, 19. Whether “solubilizer” in the patent includes co-solvents is important in this litigation, as Defendant’s formulations allegedly include one particular co-solvent, polyethylene glycol 400 (herein “PEG 400”).² *See* Pl. Brief, Ex. 20 (ANDA excerpt). Prior to Judge Reed’s opinion, Defendant contended that “solubilizer” should be read to include surfactants, but not co-solvents. Defendant asserted that, in prosecuting the ‘081 patent, the inventor had waived co-solvents, such as PEG 400, as

² The parties do not dispute that co-solvents can be used as solubilizers; in fact, the parties agree that PEG 400 can be used as a co-solvent solubilizer. *See* Transcript of Oral Argument Hearing (Jan. 30, 2003) at 13-14, 57.

appropriate solubilizers for use in the invention disclosed in the patent.

Judge Reed considered the prosecution history, the patent specification and other intrinsic evidence, and found that the inventor had not clearly disavowed non-surfactant solubilizers. *See* Conclusions of Law at 19. While Judge Reed did not explicitly conclude that “solubilizer” within the patent covers the co-solvent PEG 400, he found that “solubilizer” does include co-solvents, generally.³ Of course, any particular co-solvent, such as PEG 400, can only be considered a solubilizer, within a given device, if it *functions as a solubilizer* when it interacts with other components in that device. Thus, under Judge Reed’s claim construction, the patent covers any co-solvent, within a particular drug formulation, if that co-solvent would function as a solubilizer within that formulation. Whether PEG 400 functions as a solubilizer in Defendant’s products will be considered *infra* in Part IV.B.1.

3. *The Kawata Patent*

Judge Reed also considered Defendant’s argument that the inventor of the ‘081 patent disclaimed certain subject matter covered by a prior art patent, referred to herein as the “Kawata patent.” *See* United States Patent 4,673,564 (issued June 16, 1987) (inventors, Hiroitsu Kawata, et al.). Defendant argued during claim construction that Plaintiff was only able to obtain the ‘081 patent by distinguishing the ‘081 patent’s subject matter from Kawata.

The Kawata patent relates to “a sustained release pharmaceutical composition of a solid medical material.” *Id.* (col. 1, ln. 17). Specifically, one object of the Kawata invention was to

³ In response to Defendant’s motion for reconsideration, Judge Reed issued an additional Memorandum, in which he wrote: “I had previously determined after a thorough review of the prosecution history that Astra had not clearly disavowed claim coverage of all solubilizers, including PEG 400. I find no reason to change that conclusion.” Memo. (Oct. 3, 2002) at 6.

provide a sustained release pharmaceutical composition of the drug nicardipine, which has low solubility in the intestines. *See id.* (col. 2, lns. 14-16; col. 3, ln. 42). The Kawata invention is a process by which a solid medical material (*i.e.* nicardipine) is compounded with polyethylene oxide and at least one “basic substance” – the “first component” – such as, for example, hydroxypropylmethyl cellulose. *Id.* (col. 1, lns. 50-56). Kawata also teaches an optional second basic substance, the “second component.” *See id.* (col. 1, lns. 66-68). Kawata suggests, only by way of example, that the second component may be a surfactant (also known as a “surface active agent”), or polyethylene glycol (*i.e.* PEG 400). *See id.* (col. 2, ln. 1; col. 5; ln. 65).

It is important to note that the Kawata patent actually teaches against the use of solubilizers. *See id.* (col. 3, lns. 49-52). As Kawata explains, the inventors “found that a sustained release pharmaceutical composition of nicardipine can be obtained by using amorphous nicardipine *without adding any substance improving the solubility in the intestines.*” *Id.* Thus, although examples of the second component include surfactants and PEG 400, Kawata’s process does not make use of these substances *as solubilizers*. Earlier in this litigation, at a *Markman* hearing, Judge Reed “specifically asked defendant to show where in the Kawata patent PEG 400 was used as a solubilizer. Defendant responded by directing the court to Example 2 and highlighting that PEG 400 is used; however, Mutual never explained how it is used *as a solubilizer.*” Conclusions of Law at 16-17 (citation to transcript omitted).

Kawata describes a process in which the medical material and the first component (and, optionally, the second component) are dissolved in a volatile solvent such as ethanol, “singly or in combination,” and then the volatile solvent is removed by drying. *See id.* (col. 2, ln. 24-30). The result is a fine powder in which the medical material is dissolved “uniformly in amorphous

form in the basis substance(s).” *See id.* (col. 2, lns. 33-36). Finally, polyethylene oxide is mixed with the fine powder, resulting in a sustained release pharmaceutical composition. *See id.* (col. 2, lns. 36-39).

Defendant has placed great emphasis on the fact that Kawata lists PEG 400 as an example of the optional second component. Defendant argued before Judge Reed that, in order to obtain the ‘081 patent, Plaintiff disavowed the use of PEG 400, and other non-surfactant solubilizers, thereby limiting the ‘081 patent to surfactant type solubilizers. In response, Plaintiff argued that no such disclaimer had occurred, because Kawata and the ‘081 patent involve entirely different processes altogether. Specifically, Plaintiff contended, Kawata does not describe using PEG 400 as a solubilizer, and actually teaches against the use of solubilizers. *See* Conclusions of Law at 17-18. Rather, Plaintiff asserted that, in Kawata, the function of PEG 400 is to aid in Kawata’s “co-precipitation” process, not to serve as a solubilizer. *Id.* at 16.

Based upon a thorough consideration of the Kawata patent and the prosecution history of the ‘081 patent, Judge Reed found that Plaintiff had not clearly disavowed non-surfactant solubilizers, such as PEG 400. *See id.* at 19. The Court held as follows:

[T]he prosecution history indicates that Astra did not distinguish its patent from Kawata (1) on the ground of a particular solubilizer because not only does Kawata use an entirely different process, but the specification teaches against solubilizers; and (2) the claims do not require surfactant type solubilizers because Kawata discloses both surfactants and co-solvents as possibilities for the optional second component. It is further noted that Astra points out that nowhere in the prosecution history did Astra define nonionic solubilizer as excluding PEG 400. I therefore conclude that the prosecution history does not limit the claim term nonionic solubilizer beyond its ordinary meaning.

Id.

Judge Reed's opinion resolved several important issues regarding the '081 patent and Kawata. These conclusions can be summarized as follows: 1.) The '081 patent and Kawata use entirely different processes; 2.) the inventor of the '081 patent distinguished Kawata as an entirely different process; 3.) whereas the '081 patent requires a solubilizer, Kawata specifically teaches against the use of any component in Kawata (*i.e.* PEG 400) as a solubilizer; 4.) the inventor of the '081 patent distinguished Kawata on the ground that Kawata teaches against solubilizers; 5.) Kawata discloses both surfactants and co-solvents (*i.e.* PEG 400) as possibilities for the optional second component; and 6.) in distinguishing Kawata, the inventor of the '081 patent could not have waived co-solvents (thereby limiting the '081 patent to surfactants) because Kawata discloses both surfactants and co-solvents. *See id.* at 15-19.

Despite Judge Reed's comprehensive consideration of the Kawata disclaimer issue during claim construction, Defendant now, at the summary judgment stage, raises new arguments relating to Kawata and the prosecution history of the '081 patent.

B. Defendant's New Claim Construction Argument

Now, following Judge Reed's claim construction, in response to Plaintiff's motion for summary judgment, Defendant raises a new issue of claim interpretation, concerning the following phrase within claim 1 of the patent: "a solution or dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer." Defendant's new position is that the word "in" should be construed to mean "in and only in." Defendant's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ("Def. Brief") at 6. Defendant contends that, under the proper interpretation of "in," the patent is limited to a solution in which an effective amount of the active compound is dissolved *in and only in the solubilizer*, and in

nothing else.⁴

This is significant, Defendant claims, because in Defendant's formulations, the active compound felodipine is "intermixed" with not only PEG 400 (which may or may not function as a solubilizer), but also with one or more additional substances, such as ethanol (a volatile solvent) or polyvinyl pyrrolidone ("povidone" or "PVP"). *Id.* at 1. Defendant stresses that, in its formulations, the felodipine, the PEG 400, and various other components (*i.e.* ethanol and PVP) are all mixed together into a "homogenous composition," which is then dried. *See id.* at 7. Thus, Defendant argues, in its products the felodipine and the PEG 400 "are never intermingled in the absence of another component." *Id.* Under Defendant's suggested interpretation of the word "in," the '081 patent would cover only formulations in which an "effective amount" of the active compound is entirely dissolved or dispersed in the nonionic solubilizer alone.

Defendant highlights two statements made by the inventor in an amendment filed with the PTO. Defendant claims that these two statements prove the inventor limited its invention to a formulation in which the active compound is entirely dissolved in a solubilizer only, and not in any third substance. *See* Def. Brief at 6. Both of these statements were apparently made in attempting to distinguish the invention of the '081 patent from the prior art Kawata patent. As explained above, Kawata teaches a "first component" and an optional "second component;" the second component can be, as an example, PEG 400. Though PEG 400 can be used, generally, as a solubilizer, the Kawata patent specifically teaches that solubilizers should not be used. *See*

⁴ Plaintiff asserts that it is too late for Defendant to raise new arguments concerning claim construction. However, because a complete and proper understanding of the patent claims is necessary in order for this Court to determine whether Defendant has infringed those claims, this Court will consider Defendant's new arguments.

supra Part III.A.3.

The first statement at issue was made in relation to a May 11, 1988 claim amendment, in response to an initial rejection by the PTO based, in part, on Kawata's prior art. *See* Def. Brief, Ex. F. The inventor sought to distinguish Kawata by demonstrating that Kawata does not even make use of solubilizers, at least not in any appreciable amount. *See id.* at 5, lns. 7-11, 19-21. The inventor pointed out, to the PTO, that Kawata teaches against using any "substance improving the solubility in the intestines." *Id.* (*quoting* Kawata, United States Patent 4,673,564 (col. 3, lns. 49-52)). Of course, the use of a solubilizer is a major element in the '081 patent. Thus, the inventor argued, Kawata "provides no guidance toward the present invention." *See id.*, lns. 23-24.

The inventor also argued, in the alternative, that even if the second component in Kawata were used as a solubilizer, the active compound would be "principally" dissolved in the first component.

Only one component of [Kawata's] formulations could be a "nonionic solubilizer" . . . i.e. Kawata's optional 2nd component of the basic substance. Even if the drug in Kawata's formulations can be said to be dissolved or dispersed, however, it is not in the 2nd component alone, but principally in the required 1st component of the basic substance.

Id., Ex. F at 4-5. Defendant wishes to lift this remark out of context, to show that, in order to overcome Kawata, the '081 patent's inventor limited its coverage to solutions in which the active compound is dissolved entirely in the solubilizer, and not also in something else. More specifically, Defendant suggests that because Kawata describes a solution in which an active compound is mingled with several different components (including a volatile solvent), the '081

patent's inventor was compelled to disclaim any solution in which the active compound is not dissolved 100-percent in the solubilizer alone. This Court is satisfied that the inventor made no such disclaimer.

The inventor's remarks to the PTO were seemingly made in the context of distinguishing Kawata as an entirely different process, in that Kawata did not even utilize solubilizers. The inventor set forth an alternative argument that, even if Kawata used solubilizers, the active compound would not be "principally" in the solubilizer. All that the inventor conceded was that, if Kawata contains a solubilizer as its second component, the Kawata active compound is principally dissolved in the first component, not the solubilizer. That is entirely different from a wholesale disclaimer of all solutions in which the active compound is dissolved in both a solubilizer and another substance, such as a volatile solvent. Accordingly, the prosecution history excerpt relied upon by Defendant does not clearly establish that the inventor surrendered coverage "with reasonable clarity and deliberateness," with respect to solutions in which the active compound is not 100-percent dissolved in the solubilizer alone. *Schumer, supra*, 308 F.3d at 1313.

Defendant cites a second passage from the same claim amendment filed with the PTO, which Defendant claims establishes a disclaimer of "volatile solvents." In the amendment, the inventor asserted that "manufacture of the preparations of the invention does not involve the use of volatile solvents as does Hegasy [another prior art patent]." Def. Brief, Ex. F, at 8, lns. 16-17. This statement, on its face, demonstrates a limited disclaimer, only in that the '081 patent does not incorporate volatile solvents.

The disclaimer of volatile solvents is consistent with Plaintiff's position, throughout the

prosecution and throughout this litigation, that the Kawata patent is distinguishable as an entirely different process from the '081 patent. Just as the inventor pointed out to the PTO that Kawata does not use solubilizers, the inventor also pointed out that Kawata utilizes volatile solvents, whereas the '081 patent does not. But the inventor never told the PTO that the '081 patent should exclude all preparations in which a volatile solvent is used at all.

Claim 1's express limitation, "in a semi-solid or liquid nonionic solubilizer" applies to all solutions in which the active compound is dissolved or dispersed in a nonionic solubilizer. The specification and prosecution history do not suggest that a narrower interpretation should apply. Thus, an accused formulation will meet this claim element even though the alleged infringer has also added to the accused formulation some extra ingredients, such as PVP or a volatile solvent like ethanol. *Cf. Mannesmann, supra*, 793 F.2d at 1283 ("The presence of additional elements is irrelevant if all the claimed elements are present in the accused structure."); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 702 (Fed. Cir. 1983) ("It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device.").

As noted above, courts interpret claim language with a "heavy presumption" in favor of the "ordinary meaning" of terms. *Prima Tek, supra*, 2003 WL 245558, at *3. Defendant has failed to cite any case law justifying a conclusion that the preposition "in" is synonymous with the phrase "in and only in;" as every college student studying logic knows, they are not considered synonymous.

Defendant cites *Key Pharmaceuticals v. Hercon Laboratories Corp.*, 161 F.3d 709 (Fed. Cir. 1998), in which the Federal Circuit construed the term "pharmaceutically effective amount."

However, the *Key Pharmaceuticals* decision pertains to a patent for a transdermal adhesive patch, not an oral pharmaceutical formulation. After reviewing the facts and analysis in *Key Pharmaceuticals*, this Court is convinced that that case is totally inapposite to the question before this Court, *i.e.*, whether the '081 patent, which is limited to an "effective amount" of the active compound "in" a solubilizer, can cover only solutions in which the active compound is totally dissolved in the solubilizer alone.

Likewise, Defendant relies on *Hazani v. U.S. Intern. Trade Com'n*, 126 F.3d 1473 (Fed. Cir. 1997), in which the court construed the phrase "integrally formed in":

Although the term "integrally formed in" is not defined in the written description portion of the specification, the word "integral" means "complete" or "entire," and the word "in," as used in this context, means "indicating a point or place thought of as spatially surrounded or bounded." *See Webster's New International Dictionary* 1253, 1290 (2d ed.1939).

Hazani has not given us any reason to depart from the ordinary meaning of those words. Accordingly, the term "integrally formed in," as used in claim 14, requires that the bit line be formed entirely within the substrate.

Id. at 1480. *Hazani* is irrelevant to the instant case not only because it involved a semiconductor memory cell technology bearing no comparison to the invention of the '081 patent, but also because the *Hazani* court interpreted the word "in" within the context of the larger phrase "integrally formed in."

In sum, the intrinsic evidence presented to this Court with respect to the '081 patent does not suggest, as Defendant contends, that the word "in" must be read as "in and only in." Def. Brief at 6. Nothing in the patent or prosecution history suggests that the patent can only cover solutions in which the active compound is dissolved in and only in the solubilizer, and in nothing

else. Nor does the intrinsic evidence cited by Defendant prove that an accused product can escape infringement simply because it includes a third ingredient (such as ethanol or PVP), intermixed with the active compound and solubilizer.

IV. Step Two – Infringement

Plaintiff moves for summary judgment on the issue of literal infringement, with respect to five claims in the ‘081 patent: claims 8, 12, 14, 15 and 17.

A. Sources of Plaintiff’s Infringement Evidence

Plaintiff contends that its evidence of infringement need not exclusively rely on chemical or pharmacological properties of the various ingredients, but can also rely on admissions made by Defendant in various circumstances. In this Court’s opinion, the evidence of infringement can include the chemical and pharmacological analysis, but can also include admissions of different types.

I. ANDA

The first alleged admissions are the statements which Defendant made in its ANDA. Although these might not necessarily be characterized as “admissions,” they are clearly the Defendant’s statements and they are probative as to whether Defendant’s product infringes on Plaintiff’s patent. The cases are well established that statements in the ANDA can be used to determine whether the product specified in the ANDA will infringe an existing patent. *See, e.g., Abbott Laboratories v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (stating that “an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry”). The details concerning statements made in Defendant’s ANDA are reviewed *infra* in Part IV.B.

It is perhaps obvious, but relevant to note, that Defendant has not sold any of its generic felodipine products, and therefore there cannot be any chemical analysis based on Defendant's actual products in the stream of commerce. Therefore, the analysis must be confined to Defendant's written description of the product it proposes to sell, as well as Defendant's statements in support of the ANDA and in other proceedings. The Federal Circuit has explained that, where an infringement claim is premised upon the defendant's filing of an ANDA, the court must focus its infringement inquiry "on what is likely to be sold following FDA approval" of the defendant's proposed product. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). As the Court of Appeals noted, "this hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support," as well as "other pertinent evidence provided by the parties." *Id.* at 1569-70. The Federal Circuit has also recently observed that if the defendant's ANDA "defines a property of a compound such that it must meet a limitation of an asserted claim, then there will almost never be a genuine dispute of material fact that the claim is infringed with respect to that limitation." *Abbott*, 300 F.3d at 1373.

2. Deposition of Defendant's Officer

In addition to the ANDA itself, Plaintiff has also submitted the deposition testimony of Dr. Spiro Spireas, Ph.D., Defendant's Vice President of Research and Development. Defendant argues that Dr. Spireas's testimony was not on behalf of Defendant, but only in his personal capacity. *See* Def. Brief at 14. As the deposition was taken pursuant to Rule 30(b)(6), it is quite obviously the deposition of the Defendant itself and can be used against the Defendant. *See* Fed. R. Civ. P. 30(b)(6) (requiring deponent organization to designate officers, directors or other persons "who consent to testify on its behalf"); *Resolution Trust Corp. v. Farmer*, Civ.A. No. 92-

3310, 1994 WL 317458, at *1 (E.D. Pa. June 24, 1994) (noting “purpose behind Rule 30(b)(6) is to create testimony that will bind the corporation.”).

Dr. Spireas is not only Defendant’s Vice President of R&D, but also was directly involved in the development of Defendant’s felodipine formulations. *See* Pl. Brief, Ex. 46 (deposition transcript), at 379-80. In the deposition, he referred to himself as the “father figure” of the felodipine formulations. *Id.* at 380. In its deposition notice, Plaintiff informed Defendant that the subjects of the deposition would include the “development of the formulation of each of Mutual’s Proposed Generic Felodipine Products,” as well as the “properties, uses, functions or performance of each component of each of the Proposed Generic Felodipine Products.” Pl. Brief, Ex. 48 (notice). Accordingly, Dr. Spireas’s deposition testimony regarding Defendant’s accused products may properly be considered admissions of Defendant.

3. Product Development Reports

Plaintiff has also submitted three Mutual internal product development reports (“PDR”s), authored by Defendant’s product development personnel, including Dr. Spireas. Defendant created one PDR for each dosage of its anticipated generic felodipine product. The two PDRs related to Defendant’s 2.5 mg and 5 mg dosages were based largely on the 10 mg PDR, and incorporated that PDR by reference. *See* Pl. Brief, Ex. 13, at M037421; Ex. 14, at M037107.

Defendant contends that the statements in its PDRs amount to “mere conjecture, hypothesis and theory,” and cannot constitute “evidence” as to the nature of Defendant’s final products. *See* Defendant’s Supplemental Memorandum in Opposition to Plaintiff’s Motion (herein “Def. Supp.”) at 19. As Dr. Spireas explained in his deposition, the PDRs contain a “comprehensive discussion of all the issues, all of the major, if you will, issues that were

involved in the development of this product.” Pl. Brief, Ex. 46, at 379-80. Moreover, the PDRs themselves explain that the “target” of Defendant’s product development was the submission of an ANDA for generic felodipine tablets in 10, 5 and 2.5 mg dosages. *Id.*, Ex. 9, at M036583.

To rebut any relation between the PDRs and Defendant’s ultimate product, Defendant refers to the contents of its PDRs as mere “hypothesis,” as to the nature or properties of Defendant’s formulations. Def. Brief at 15 (citing Def. Brief, Ex. H (10 mg PDR), at M036588). Defendant has not explained why the PDRs would have been written if they did not relate specifically to the felodipine products developed by Defendant. Accordingly, in deciding the present summary judgment motion, this Court will consider any statements contained in Defendant’s PDRs, along with all other evidence submitted.

4. Judicial Admissions

Plaintiff also relies on certain other statements which are in the nature of judicial admissions, being statements made by Defendant’s counsel in the proceedings before Judge Reed. Judicial admissions “are admissions in pleadings, stipulations, etc. and which do not have to be proven in the same litigation.” *Giannone v. U. S. Steel Corp.*, 238 F.2d 544, 547 (3d Cir. 1956).

Plaintiff contends that Defendant’s counsel admitted, earlier in this litigation, that its product contains every element of the patent’s claims, except for one element – the “nonionic solubilizer.” For instance, at an October 12, 2001 hearing, Defense counsel told the Court, “[w]e don’t dispute that we have all the other claim elements in the patent claim. So the defense from an infringement standpoint is really just that, the non-ionic solubilizer that’s claimed in the patent can’t cover the PEG-400.” See Pl. Brief, Ex. 4 (Transcript), at 112-13. Also, in an October 5,

2001 letter to Judge Reed, Defense counsel advised the Court that “the only contested issue for decision on the subject of infringement is the following: Whether PEG 400 [a component of Defendant’s products] is a ‘solubilizer’ as this claim term is properly construed in view of the plain language of the claim, the specification and the prosecution history.” *See id.*, Ex. 21, at 2.

Defendant asserts that its statements should not be considered because their counsel was merely advocating Defendant’s position on the claim construction issues, and it would not be fair to hold the statements of counsel in that context against Defendant in the infringement context. Generally, to be binding, judicial admissions must be “unequivocal.” *Glick v. White Motor Co.*, 458 F.2d 1287, 1291 (3d Cir. 1972). Moreover, as the Third Circuit has pointed out, in a non-patent context, the scope of judicial admissions is “restricted to matters of fact which otherwise would require evidentiary proof, and does not include counsel’s statement of his conception of the legal theory of a case.” *Id.* This Court believes the statements by Defendant’s counsel were more than legal contentions, and, thus, may be considered along with the other evidence. *See, e.g., Zapach v. Dismuke*, 134 F.Supp.2d 682, 693 (E.D. Pa. 2001) (finding defendant’s admissions in deposition conclusive as to facts admitted); *Loral Fairchild Corp. v. Victor Co. of Japan, Ltd.*, 911 F.Supp. 76, 81 (E.D.N.Y. 1996) (holding plaintiff was estopped from changing its patent infringement theory following discovery, where plaintiff had consistently maintained a different position on liability from outset of litigation).

The Court need not decide whether it would rest infringement on judicial admissions alone, because, in this case, the judicial admissions follow and are consistent with the statements made by Defendant’s representatives in a deposition and in the ANDA itself. Thus, although the Court believes it does not have to rely on judicial admissions alone, because there is a

consistency throughout the evidence, the judicial admissions may be considered along with the other evidence.

B. Comparison on Defendant's Proposed Products to the '081 Patent Claims

As explained above, a patent claim covers an accused device if that device embodies every element of that claim. *See, e.g., Carroll Touch*, 15 F.3d at 1576. Claims 8, 12, 14 and 15 of the '081 patent are dependent on claim 1, whereas claim 17 claims the process of the invention. Although Plaintiff does not here assert infringement of claim 1, *see* Pl. Brief at 2, this Court must nevertheless determine whether Defendant's products contain every element of claim 1, in order to decide whether Defendant has infringed dependent claims 8, 12, 14 and 15.

1. *Claim 1 of the '081 Patent*

Claim 1 comprises "a solution or dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer, wherein the amount by weight of the solubilizer is at least equal to the amount by weight of the active compound, and a release controlling system to provide extended release." United States Patent 4,803,081. This Court must determine whether each of the three elements of claim 1 is present in the accused formulations.

a. "A solution or dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer"

To be effective as a drug, felodipine needs to get through the intestine. The parties agree that felodipine is insoluble in water. The use of a "solubilizer," together with an extended release mechanism, helps to get felodipine through the intestine and into the bloodstream. As noted above, Judge Reed, in construing the claims, held that "solubilizer" should be given its ordinary

meaning, including surfactant and co-solvents.

Defendant argued during claim construction that the '081 patent only covers surfactants, and that PEG 400, which is a co-solvent, not a surfactant, does not qualify as a solubilizer. Because Judge Reed held that a non-ionic solubilizer, as claimed by Plaintiff, includes all types of solubilizers, including co-solvents, this Court holds that PEG 400, a co-solvent used by Defendant, can function as a solubilizer.

Defendant seemingly does not dispute that its formulations contain an active compound, felodipine, which is “in solution.” Def. Brief at 9. Nevertheless, Defendant contends that, in its products, the active compound is not dissolved in any chemical which functions as a solubilizer in Defendant’s products. Moreover, Defendant’s position is that, even if PEG 400 functions as a solubilizer in Defendant’s formulations, the active compound is not exclusively dissolved “in and only in” that solubilizer. *Id.* at 6.

(1.) Evidence Presented By Plaintiff on the “Solubilizer” Claim Element

Defendant’s manufacturing process undeniably involves the use of liquid PEG 400. *See* Pl. Brief, Ex. 20 (excerpt from ANDA); Ex. 26 at M002574. Moreover, Defendant’s ANDA itself states that PEG 400 is used as a “solubilizer” in Defendant’s products. *See* Pl. Brief, Ex. 20. The ANDA includes several Unit and Batch Composition charts, relating to Defendant’s proposed felodipine dosages. In each of these charts, the left column lists the components of Defendant’s proposed formulations, while the right column states the “function” of the corresponding ingredient. Right across from PEG 400, each chart simply reads “solubilizer.”⁵

⁵ On November 15, 2000, two months after Plaintiff commenced this patent infringement lawsuit, Defendant filed an amendment to its ANDA with the FDA, changing the stated function of PEG 400 to “Drug Carrier/Cosolvent/Drug Dissolution Enhancer.” *Id.*, Ex. 31.

Id.

The testimony of Dr. Spireas also lends support to the conclusion that PEG 400 is a solubilizer in Defendant's products. Doctor Spireas was asked about certain experiments he had performed, involving felodipine. Dr. Spireas characterized PEG 400 as a "cosolvent solubility enhancer" with respect to these experimental formulations. Pl. Brief, Ex. 46 (deposition transcript), at 324, Ins. 8-13. At another point, he described PEG 400 as a "cosolvent, which happens to be a solubility enhancer, which happens to be a nonvolatile solvent." *Id.* at 333, Ins. 24-25. Elsewhere, the witness explained that PEG 400 "increases the solubility of water-insoluble drugs in water." *Id.* at 335, Ins. 8-9.

As discussed above, Judge Reed determined that the term "nonionic solubilizer" in the '081 patent should be read according to its ordinary meaning, *i.e.*, a nonionic compound "that increases the solubility of a substance in a particular solvent." Conclusions of Law at 19. Dr. Spireas, as the R&D officer who developed Defendant's accused formulations, acknowledged, at least tacitly, that the function of PEG 400 is to increase the solubility of felodipine in water. Therefore, Dr. Spireas's testimony is strong evidence suggesting that the PEG 400 in Defendant's products is indeed a solubilizer.

Finally, Defendant's product development reports explain that the "nonvolatile solvent," PEG 400 "would enhance by a cosolvency principle the solubility of felodipine." Pl. Brief, Ex. 9, at M036587. The PDRs also reveal that, in the felodipine formulations developed by Defendant, the drug is "already in solution in the nonvolatile solvent," PEG 400. *Id.* at M036588. Moreover, Defendant's internal laboratory research documents confirm that, in Defendant's manufacturing process, the felodipine "goes into solution" when it is introduced into

a mixture of PEG 400 and ethanol. *See* Pl. Brief, Ex. 26, at M004220.

(2.) Defendant's Evidence and Arguments

In support of its position that the active compound in the accused formulations is not dissolved “in” the PEG 400, Defendant has submitted two expert affidavits. *See* Def. Supp., Exs. H and I. In the first affidavit, James A Ibers, Ph.D., states that he studied samples of Defendant’s felodipine products using X-ray diffraction techniques. *See id.*, Ex. H. ¶ 11. Per the expert’s observations, no felodipine “crystals” were present in Defendant’s formulations; rather the felodipine was in “amorphous” form. *Id.* ¶ 15. The affidavit of Dr. Natalie Lazarowych is based on her analysis of scanning electron micrographs and light micrographs performed on Defendant’s formulations. *See id.*, Ex. I ¶ 7. The expert stated that, in her opinion, “the location of the felodipine could not be determined.” *Id.* ¶ 9. Further, in the expert’s view, “it could not be determined if the felodipine was dissolved or dispersed in PEG 400.” *Id.*

As set forth above, Plaintiff has submitted numerous admissions by Defendant, which affirmatively demonstrate that the felodipine is dissolved in the PEG 400 in the accused products. Accordingly, under Fed. R. Civ. P. 56(e), Defendant must come forward with at least some evidence suggesting that the felodipine is not dissolved in a solubilizer. The two affidavits submitted merely state that, in the experts’ views, it cannot be determined whether or not the felodipine is in the PEG 400. These affidavits also suggest, vaguely, that the felodipine appeared to be in “amorphous” form. Defendant’s expert affidavits fail to reach any definite conclusion whatsoever. By contrast, Plaintiff has positively shown that the felodipine formulations, which Defendant intends to market, would contain an active compound dissolved in PEG 400, acting as a solubilizer.

Aside from its affidavit evidence, Defendant again raises an argument as to “disclaimer.” Defendant stresses that it cannot be infringing the ‘081 patent because it is merely following the co-precipitation process described in the prior art Kawata patent, which – Defendant still urges – the inventor of the ‘081 patent disclaimed entirely.

As explained above, the inventor did not disclaim the entire subject matter taught in Kawata; rather, the inventor only distinguished the ‘081 patent from Kawata, as a totally unrelated process. *See supra* Parts III.A.3 and B. Although the inventor seemingly disclaimed volatile solvents – because volatile solvents are not a component of the ‘081 patent – that does not mean that the inventor disclaimed all preparations in which a volatile solvent is intermixed along with the active compound and solubilizer. *See* Part III.B, *supra*. Moreover, although the inventor distinguished Kawata as not contemplating a solubilizer element, that does not mean that the inventor disclaimed all solutions in which the active compound is not 100-percent dissolved in a solubilizer, and in nothing else. *See supra id.*

While it is true that Defendant’s process and the Kawata process share certain common components, Defendant uses PEG 400 as a solubilizer, whereas Kawata specifically teaches against the use of any component as a solubilizer. *See* Conclusions of Law at 17-18. On that ground alone, Defendant’s process departs from the technique disclosed in Kawata. Moreover, even assuming that Defendant’s products and process in fact follow Kawata to the letter, the mere fact that an accused infringer is “practicing the prior art” does not preclude a finding of literal infringement. *Tate Access Floors, Inc. v. Interface Archit. Resources, Inc.*, 279 F.3d 1357, 1365 (Fed. Cir.2002). Though a prior art patent would certainly be relevant to a claim of patent invalidity, it can be no defense to infringement – an entirely separate determination. *See id.* at

1367.

Additionally, Defendant highlights the fact that it first mixes ethanol with the PEG 400, before dissolving the felodipine. But this cannot free Defendant's formulations from the '081 patent's coverage. The '081 patent is not limited to solutions in which the active compound is dissolved "in and only in" the solubilizer, and in nothing else. *See* Part III.B, *supra*. Moreover, all of the ethanol Defendant uses is evaporated during the manufacturing process. As Defendant's ANDA explains, ethanol (denatured alcohol) does "not appear in the final product." Pl. Brief, Ex. 20, at M002933. Defendant's PDRs also state that ethanol "does not appear in the final product." *Id.*, Ex. 9, at M036600. Thus, even if it may be said that the felodipine is dissolved partially in both the ethanol and PEG 400, the ethanol is entirely dried off during Defendant's process, making it impossible for any felodipine to remain dissolved in ethanol in the final formulations.

Finally, Defendant claims that some of the statements contained in the PDRs and the deposition of Dr. Spireas pertain not to Defendant's products, but rather, to a separate technology called "LiquiSolid" systems, for which Dr. Spireas himself holds a number of patents. Def. Supp. at 18. However, as explained in the PDRs, Defendant's formulations were "based on" LiquiSolid systems and the use of PEG 400 as a "carrier/cosolvent." Pl. Brief, Ex. 9, at M036587. The purpose of the PEG 400 in Defendant's products is to "enhance by a cosolvency principle the solubility of felodipine." *Id.* Therefore, even if Defendant could successfully distinguish LiquiSolid systems from Defendant's ultimate products, Defendant cannot disprove the use of PEG 400 as a solubilizer in those ultimate products.

(3.) Presence of the "Solubilizer" Element in Defendant's Products

At oral argument defense counsel asserted that a genuine issue of fact for trial existed as to whether Defendant's product is dissolved in a substance that fits with Judge Reed's definition of a solubilizer. Defense counsel (*See* Transcript of Oral Argument Hearing (Jan. 30, 2003) at 46-47) asserted that, in Defendant's products, the active compound is dissolved differently than in the '081 patent. Defendant claims that it dissolves the active compound (felodipine) in ethanol, which is not a solubilizer. Felodipine is well known to be fully soluble in alcohol. Defendant asserts that its product does not infringe the patent because at no point during Defendant's process does the felodipine and PEG 400 come into intimate contact with each other alone, in the absence of other substances. Defense counsel asserted that, therefore, Defendant's process is so different from the Plaintiff's process, that it creates an issue of fact as to whether Defendant's process is covered by Judge Reed's definition of the Plaintiff's claim. Thus, Defendant asserts that, even assuming PEG 400 is a solubilizer, the manner in which Defendant uses it does not make Defendant's product infringe the patent.

Defendant's counsel's argument must be rejected. First, as noted above, the affidavits which Defendant has submitted do not fully support the argument of counsel. Second, defense counsel's argument is contradicted by the many statements by Defendant, reviewed above, that demonstrate that felodipine is dissolved in PEG 400 in the Defendant's product. Lastly, Judge Reed's definition of a solubilizer is justifiably broad enough to cover Defendant's use of PEG 400. Assuming *arguendo* that Defendant dissolves the active compound first into the ethanol, the fact that Defendant uses PEG 400 as a solubilizer – in which to dissolve the felodipine to any extent – warrants a conclusion that Defendant's products contain an active compound which is dissolved or dispersed in a nonionic solubilizer.

b. “Wherein the amount by weight of the solubilizer is at least equal to the amount by weight of the active compound”

Next, the patent requires that the amount by weight of the solubilizer be at least equal to the amount by weight of the active compound. Defendant’s ANDA and PDRs reveal that, in the allegedly infringing formulations, the solubilizer PEG 400 outweighs the active compound, felodipine, by 4.5 times, 9 times, or 18 times, depending on the drug dosage. *See id.*, Exs. 20 and 31 (ANDA excerpts); Ex. 14, at M037112. This meets the weight-ratio limitation of claim 1.

c. “A release controlling system to provide extended release”

Finally, claim 1 requires a “release controlling system to provide extended release.” Judge Reed construed the term “extended release,” throughout the patent, as meaning “releasing the active ingredient from the dosage form over time in a manner that reduces the dosage frequency as compared to immediate release dosage forms.” Conclusions of Law at 21. Defendant’s ANDA reveals that the accused formulations contain hydroxypropyl methylcellulose (herein “HPMC”), the function of which is to provide extended release. *See id.*, Exs. 20 and 31 (ANDA excerpts). Defendant’s PDRs also list this ingredient as an extended release agent. *See id.*, Ex. 14, at M037112. Accordingly, this final element of claim 1 is present in Defendant’s products. Therefore, Plaintiff has met its burden of proving that Defendant’s products encompass every element of claim 1.

2. *Claim 8 of the ‘081 Patent*

Claim 8 reads, in its entirety: “A preparation according to claim 1 wherein the active compound comprises one or more substituted dihydropyridines.” U.S. Patent 4,803,081. Because claim 8 refers to the preparation set forth in claim 1, claim 8 must be construed as

including all of claim 1's limitations, in addition to the limitation that the active compound must comprise one or more substituted dihydropyridines. The cardiovascular drug felodipine is undisputedly a dihydropyridine. *See* Pl. Brief, Ex. 5 (Parties' Joint General Glossary of Technical Terms). The active compound in Defendant's formulations is felodipine. *See* Pl. Brief, Ex. 20. Accordingly, the dihydropyridine element of claim 8 is met. This Court has found *supra* that Defendant's products infringe claim 1. Hence, there remains no genuine issue of material fact as to Defendant's infringement of claim 8.

3. Claim 12 of the '081 Patent

Claim 12 covers "[a] preparation according to claim 1 wherein the release is controlled by a hydrophilic gel system." U.S. Patent 4,803,081. As explained above, this Court has interpreted the term hydrophilic gel system to mean "a delivery system of a water-soluble gel- and matrix-forming material." Conclusions of Law at 24. Plaintiff suggests that hydroxypropyl methylcellulose (HPMC), which is used in Defendant's products as an extended release agent, is a hydrophilic gel system. Defendant's ANDA states that one function of HPMC is "Matrix Forming Agent." Pl. Brief, Ex. 20. Defendant's PDRs refer to HPMC as an "extended release and matrix forming agent." *Id.*, Ex. 9, at M03660; Ex. 13, at M037426; Ex. 14, at M037112. Defendant has offered no evidence to show that this claim element is absent from its products. Therefore, there is no genuine issue of material fact as to Defendant's infringement of claim 12.

4. Claim 14 of the '081 Patent

Claim 14 covers "[a] preparation according to claim 12 wherein the hydrophilic gel system comprises hydroxypropyl methylcellulose." U.S. Patent 4,803,081. As explained above, hydroxypropyl methylcellulose (HPMC) is used in Defendant's formulations as a hydrophilic gel

system. Therefore, summary judgment of infringement is appropriate as to claim 14.

5. Claim 15 of the '081 Patent

Claim 15 covers “[a] preparation according to claim 14 wherein the hydroxypropyl methylcellulose has a hydroxypropyl content of 4-12% by weight.” U.S. Patent 4,803,081. Plaintiff has submitted a Mutual internal report to demonstrate that the hydroxypropyl methylcellulose (HPMC) used in Defendant’s formulations has a hydroxypropyl content, by weight, of between seven and twelve percent. *See* Pl. Brief, Ex. 29. Plaintiff also points to a scientific paper authored by Dow Chemical Company to show that the HPMC used in Defendant’s products has a hydroxypropyl percentage between seven and twelve percent. *See id.*, Ex. 15, at 8. Defendant has not attempted to rebut these proofs. Therefore, there is no genuine issue of material fact that Defendant’s products infringe claim 15.

6. Claim 17 of the '081 Patent

Claim 17 describes the process of the invention taught in the '081 patent.

17. A process for making a solid preparation that provides extended release of an active compound with very low solubility in water comprising
dissolving or dispersing an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer, the amount by weight of said solubilizer being at least equal to the amount by weight of the active compound, and
incorporating the resulting solution or dispersion into a suitable release controlling system to form a pharmaceutical dosage unit.

U.S. Patent 4,803,081. The process described in claim 17 involves two steps: dissolving or dispersing the active compound in a nonionic solubilizer; then, incorporating the resulting solution or dispersion into a suitable “release controlling system” to form a pharmaceutical

dosage unit.

Defendant's process involves each of the elements involved in these two steps. In its ANDA, Defendant includes a Manufacturing Process Flowchart, relating to its felodipine products. The first step described in this chart is mixing together ethanol and PEG 400. *See* Pl. Brief, Ex. 26. The very next step is to add felodipine into that mixture, then stir for eight minutes. *See id.* Subsequent steps involve adding povidone (PVP) and other substances into the total composition. Yet, per this Court's claim construction, the inclusion of ethanol, PVP or some other ingredient in Defendant's composition cannot negate the fact that the felodipine goes into solution with the PEG 400. Defendant's process also requires mixing the resulting solution with HPMC, which Defendant's own documents refer to as an "extended release agent." *See* Pl. Brief, Exs. 20 and 27. Defendant has not submitted evidence specifically rebutting Plaintiff's evidence of infringement as to claim 17. Accordingly, summary judgment is appropriate.

C. Defendant's products infringe the '081 patent.

Defendant finally contends that Plaintiff has conducted "no technical analysis on Mutual's tablets," and therefore cannot prove that those tablets embody the elements of the '081 patent. Def. Supp. at 13. Courts do not require an inventor to physically test an accused product, or produce the defendant's device, to establish infringement. *See, e.g., Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1098 (Fed. Cir. 1987). Rather, this Court may decide the present motion for summary judgment based on the numerous admissions relied on by Plaintiff. *See* Fed. R. Civ. P. 56(c) (permitting court to consider "admissions" in deciding summary judgment motion). *See also Penederm Inc. v. Alzo, Inc.*, No. Civ.A. 95-1222, 1996 WL 724766, at *3 (N.D. Cal. 1996) (stating that defendant's "own representations about the accused

composition may sufficiently demonstrate that the composition meets the elements of the claims”).

As shown in Part IV.B, *supra*, Defendant’s formulations embody every element of claims 1, 8, 12, 14, 15 and 17. This Court has compared Defendant’s proposed products, component by component, with the elements of the ‘081 patent’s claims, and concludes that no genuine issue of material fact remains as to whether Defendant has infringed the patent.

V. Conclusion

Plaintiff has met its burden of demonstrating the absence of a genuine issue of material fact, as to whether Defendant’s proposed formulations infringe claims 8, 12, 14, 15 and 17 of the ‘081 patent. Defendant has not countered Plaintiff’s evidence with “specific facts showing that there is a genuine issue for trial.” Fed. R. Civ. P. 56(e). Accordingly, this Court shall enter summary judgment of literal infringement.

An appropriate Order follows.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ASTRAZENECA AB, et al.	:	CIVIL ACTION
	:	
v.	:	
	:	
MUTUAL PHARMACEUTICAL CO., INC.	:	00-4731

ORDER

AND NOW, this 14th day of March, 2003, it is hereby ORDERED that the Plaintiffs' Motion for Summary Judgment of Literal Infringement is GRANTED.

For purposes of scheduling proceedings on Defendant's counterclaim, counsel shall confer on a schedule providing for dispositive motions and, if necessary, a trial, this calendar year. A telephone conference with counsel is scheduled for Tuesday, March 25th at 5:00 p.m. Plaintiff's counsel will initiate the call, and when all parties are on the line, call Chambers at 267.299.7520.

BY THE COURT:

MICHAEL M. BAYLSON, U.S.D.J.